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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,168	09/10/1999	TOSHIMITSU ISHIKAWA	724-P10-2589	2333

7590 07/07/2003

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WASHINGTON, DC 20006

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/07/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

89/393168

Applicant(s)

ISHIKAWA

Examiner

WEBMAN

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 3/26/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-22 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-22 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miskel et al. (US Patent No. 3,851,051) in view of Tanner et al. (US Patent No. 5,569,466).

Miskel et al., see Example 1 column 6, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited-oil solubility (diphenhydramine).. No dispersion stabilizer and fat and oil material or oil-soluble material is present.

Further, Miskel et al., see Example 50, teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited oil-solubility (sodium saccharin). No dispersion stabilizer and fat and oil material or oil-soluble material is present.

However, Miskel et al. do not teach a homogenous mixture of the medicinal liquid in the soft capsule.

Tanner et al. teach fill compositions for soft gel capsules (title) comprising an active agent dissolved or suspended in a carrier liquid (abstract). Tanner et al. teach homogenization of actives and solubilizing agents (column 4, lines 47-50, and 65-66). Water is disclosed (column 3, line 61).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a soft gel capsule comprising citrus pectin, to achieve high stability in view of Miskel et al.

As to the claimed homogenization, Tanner et al. teach that homogenization is well known in the art of making a soft gel capsule. One of ordinary skill in the art would recognize that homogenization provides a stable mixture.

Applicants argue that Miskel et al teach a rigid gel rather than a liquid suspension. However, Miskel et al disclose a suspension (column 3 lines 40-44). That remains fluid at 30-40<sup>0</sup>C during the filling of a soft gelatin capsule (column 3 line 71 – column 4 line 6). Applicants also disclose a liquid suspension at temperatures of 40<sup>0</sup>C and 50<sup>0</sup>C (page 7 line 31, page 8 line 14, page 9 line 11, page 10 line 27). Applicants are silent regarding the form of their suspension below 30<sup>0</sup>C.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

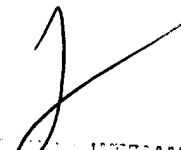
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR  
June 18, 2003



EDWARD WEBMAN  
Patent Examiner  
GROUP 1600